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OCT 23 2012

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

510(k) Owner
Osseon® Therapeutics, Inc.
2330 Circadian Way
Santa Rosa, CA 95407
Phone: 707-636-5940
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Official Contact
Keith Burger
Director of Research and Development

Device Information

Trade or Proprietary Name:	Osseoflex® SB
Common Name:	Inflatable Bone Tamp
Classification Name:	Primary: Arthroscope Secondary: Cement, Bone Vertebroplasty
Classification Panel:	Orthopedic
Regulation:	Class II per 21CFR §888.1100, Procode HRX Class II per 21CFR §888.3027. Procode NDN
Product Code(s)	OF-0005
Legally marketed device(s) to which equivalence is claimed	Kyphon Inflatable Bone Tamp, K041454, K032212, K010246, K981251 CareFusion Inflatable Bone Tamp, K103064, K093463, K090211
Reason for 510(k)	New Device
Device Description	The Osseoflex® SB is designed for use in balloon kyphoplasty. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which the physician can inflate the balloon at the distal end of the catheter. After the bone is disrupted, PMMA is injected through an Osseoflex® needle to fill the previously created void(s). An access channel is required for Osseoflex® SB placement. The Osseoflex® SB device does not create an access channel; the Osseoflex® SB is designed to follow a pre-existing channel created by an access channel device. The articulating or steering feature of the device assists the clinician in directing the device to the pre-existing channel. The Osseoflex® SB knob can be turned clockwise to aid in directing the distal portion of the device. Turning the knob counter-clockwise will relax the device and allow the

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device to be returned to its start position. The device should be manipulated only while under fluoroscopic observation with radiographic equipment that provides high quality images.

Intended Use

The Osseoflex® SB is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethymethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, such as kyphoplasty.

Summary of Technological Characteristics of the Device Compared to the Predicate Devices			
Characteristic	**New Device**	**Predicate Device**	**Predicate Device**
Trade Name	Osseoflex SB	Kyphon IBT (K041454, K032212, K010246, K981251)	Carefusion AVAmax Vertebral Balloon (K103064, K093463, K090211)
Cannula size	8G	8G	8G
Balloon Inflation Medium	60% Contrast	60% Contrast	60% Contrast
Balloon Material	Polyurethane	Polyurethane	Polyurethane
Balloon Size	15mm	10, 15, and 20mm	10, 15, and 20mm
15mm Balloon Diameter at nominal volume (2ml)	10.2mm	8.5mm	11.8mm
15mm `Balloon Length at nominal volume (2ml)	13.7mm	14.6mm	14.9mm
Balloon Shape	Cylindrical	Variable	Cylindrical
Max inflation pressure	400 psi (27 ATM)	400 psi (27 ATM)	400 psi (27 ATM)
Max inflation volume	4ml	4ml	4ml

Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence		
Performance Test Summary – Osseoflex SB		
Characteristic	**Standard/ Test/ FDA Guidance**	**Results Summary**
Inflation Pressure	Constrained Burst Test	The balloon catheter exceeded the requirements for the minimum burst pressure in a constrained environment
Inflation Volume	Unconstrained Burst Test	The balloon catheter exceeded the requirements for the minimum burst volume in an unconstrained environment
Balloon Double Wall Thickness	Calibrated Measurement	The double wall thickness of the balloon was substantially equivalent to that of the predicate devices
Summary of Clinical Tests Conducted for Determination of Substantial Equivalence		
N/A – No clinical test were conducted for this submission		
Conclusions Drawn from Non-Clinical and Clinical Data		
The results of the non-clinical tests show that the Osseoflex SB meet or exceed all performance requirements, and are substantially equivalent to the predicate devices.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Osseon® Therapeutics, Incorporated
% Mr. Keith Burger
Director of Research and Development
2330 Circadian Way
Santa Rosa, California 95407

OCT 23 2012

Re: K122533
Trade/Device Name: Osseoflex® SB
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: October 5, 2012
Received: October 11, 2012

Dear Mr. Burger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

12.0 INDICATION FOR USE STATEMENT

510 (k) Number: K122533

Device Name: Osseoflex® SB

Indication For Use:

The Osseoflex® SB is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122533